REMARKS

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections, and allow claims 1, 3-8 and 55-76, the currently pending claims. Claims 77-80 are canceled. Claims 1, 61, 64, 68 and 71 have been amended. No new matter is added.

On December 26, 2002, Applicants requested declaration of an interference between the present application and U.S. Patent no. 5,998,205. Applicants herein withdraw the request. The owner of the present application, Cell Genesys, Inc., has acquired an ownership interest in certain intellectual property owned by Genetic Therapy, Inc., including the '205 patent. As such, an interference would not be proper under § 1.602 (a), which states that "unless good cause is shown, an interference shall not be declared or continued between (1) applications owned by a single party or (2) applications and an unexpired patent owned by a single party."

Claims 1, 3-6, 8, 59, 61, 67, and 77-80 have been provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-8, 28-31, 33-34, 42 and 44-45 of co-pending Application no. 09/151,376. Applicants respectfully submit that when a provisional rejection of this type is made, it is proper to issue one of the applications and allow a terminal disclaimer to be filed in the other, and agree to provide a suitable terminal disclaimer at such time as a patent is issued.

As previously stated in Applicants response to the Office Action of January 30, 2002, Applicants have agreed to provide a terminal disclaimer for the present claims over U.S. Patent no. 5,698,443, U.S. Patent no. 5,871,726, U.S. Patent no. 6,197,293, and U.S. Patent no. 6,254,862, as appropriate, upon indication of allowable subject matter. Applicants further agree to provide a terminal disclaimer over U.S. Patent no. 6,432,700.

Claims 1, 3, 4, 6 and 55-80 have been rejected under 35 U.S.C. 102 (e) as anticipated by Gregory *et al.*, US2001/0053768.

As stated in the summary of the invention (paragraph 9), Gregory *et al.* provides a method for "amplifying the effect of the therapeutic gene carried by the replication competent adenoviral vector". The application is therefore directed at methods of increasing the expression of a therapeutic gene in the targeted tissue.

As defined by Gregory *et al.*, therapeutic genes are foreign genes expressed from the replication competent adenoviral vectors, and specifically are not present in wild-type adenovirus (paragraph 17). Such therapeutic genes could therefore not include adenovirus proteins, such as E1b, E1a, *etc.*, as such proteins are present in wild-type adenovirus. Therefore, the invention set forth by Gregory *et al.* requires elements not present in Applicants' claimed invention.

In contrast to Gregory *et al.*, Applicants invention is directed at replication competent adenovirus, which utilize cell type-specific transcriptional regulatory elements operably linked to native adenoviral genes and achieve a therapeutic result, which relies upon cytolysis of host cells and is not dependent on expression of foreign genes. The constructs are designed such that the cell type-specific transcriptional regulatory element facilitates replication of the adenovirus and corresponding death of particular host cells and not others (as described in the specification, e.g., on page 40, lines 7-9 and on page 44, lines 7-8).

Applicants further submit that, should the rejection be maintained, Gregory is not prior art to the present application by virtue of the previously submitted Declaration under 37 C.F.R. 1.131 by Applicants, which Declaration antedates the May 3, 1995 priority date of Gregory *et al.*

In view of the above amendments and remarks, Applications respectfully submit that Gregory *et al.* does not teach the presently claimed invention, because it fails to teach selective cytolysis of target cells. Withdrawal of the rejection is requested.

Claims 1, 3, 4, 6 and 55-80 have been rejected under 35 U.S.C. 102(e) as anticipated by Hallenbeck *et al.*, U.S. Patent no. 5,998,205. Applicants respectfully submit that Hallenbeck is not available as prior art under 35 U.S.C. 102(e). The '205 patent was filed in the PCT on June 7, 1995, claiming priority of a CIP parent, U.S. Patent Application Serial No. 08/348,258, filed November 28, 1994. It is clear that the effective filing date for the claims of the '205 patent can be no earlier than the June 7, 1995 filing. In fact, the file history of USSN 08/849,117 (the application which led to U.S. Patent no. 5,998,205 states that USSN 08/849,117 is a 371 filing of PCT/US95/15455, filed 11/28/95, with a 102(e) date of 7/1/97 (see Notice of Acceptance for USSN 08/849,117 mailed 8/26/97).

Under the Guidelines for Examination (OG Notices 14 January 2003, copy attached), it is stated that "Specifically, this notice provides guidance that prior art, as defined by 102(e) of the patent code in effect on November 29, 2000, includes U.S. patents, publications of U.S. patent applications and World Intellectual Property Organization's (WIPO) publications of international applications, provided such references do not directly or indirectly result from an international application filed before November 29, 2000. If a U.S. patent resulted from an international

application filed before November 29, 2000, the U.S. patent will have a prior art date per 102(e) in effect prior to November 29, 2000, which is the earlier of the date of compliance with 371(c)(1), (2) and (4) of the patent code (e.g. National Stage entry) or the filing date of the later-filed U.S. application that claimed the benefit of the international application. A U.S. or WIPO publication of an international application filed prior to November 29, 2000 will have no prior art effect under 102(e). Such publications do, however, have prior art effect under 102(a) or (b) as of their publication dates." (emphasis added)

As Hallenbeck *et al.* directly results from an international application filed before November 29, 2000, it is prior art under 35 U.S.C. 102(e) as the date it completed entry into the U.S. National Stage, and hence is not art to the present application.

Claims 1-6, 8 and 55-76 have been rejected under 35 U.S.C. 103 as unpatentable over Gregory *et al.*, taken with Bohinski *et al.*, Abe *et al.*, Grooteclaes *et al.* The Office Action states that Abe, Grooteclaes and Bohinski teach tissue specific promoters.

Applicants respectfully submit that the cited combination of references does not make obvious the claimed invention. As discussed above, Gregory *et al.* fails to teach a cytolytic replication competent adenovirus, and is directed to adenovirus as a vector to deliver therapeutic foreign genes to a targeted cell. The secondary references fail to remedy the deficiencies of Gregory *et al.* The secondary teachings disclose specific transcriptional response elements, but provide no teaching or motivation for using such elements to construct an adenovirus vector in which the adenovirus causes selective cytolysis of target cells.

In viewing the combination of cited art, a person of ordinary skill in the art would lack the guidelines necessary to practice the claimed invention. The essential feature of providing a cytolytic replication competent adenovirus is not provided in the art, and requires an inventive step well beyond routine experimentation. In view of the above amendments and remarks, withdrawal of the rejection is requested.

CONCLUSION

Applicants submit that all of the claims are now in condition for allowance, which action is requested. If the Examiner finds that a Telephone Conference would expedite the prosecution of this application, he is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any other fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number CELL-004CON.

Respectfully submitted,

Date: Oct. 27, 2003

By: Pamela Sherwood
Pamela J. Sherwood, Ph.D.
Registration No. 36,677

BOZICEVIC, FIELD & FRANCIS LLP
200 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 327-3400
Facsimile: (650) 327-3231